

## Complete Summary

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### GUIDELINE TITLE

American Academy of Orthopaedic Surgeons clinical guideline on diagnosis of carpal tunnel syndrome.

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Orthopaedic Surgeons clinical guideline on diagnosis of carpal tunnel syndrome. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2007. 72 p. [381 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
QUALIFYING STATEMENTS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY  
DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

Carpal tunnel syndrome

### GUIDELINE CATEGORY

Diagnosis  
Evaluation

### CLINICAL SPECIALTY

Family Practice  
Internal Medicine  
Neurology

Orthopedic Surgery  
Physical Medicine and Rehabilitation

## **INTENDED USERS**

Health Care Providers  
Health Plans  
Managed Care Organizations  
Physicians

## **GUIDELINE OBJECTIVE(S)**

- To improve carpal tunnel syndrome (CTS) diagnosis based on the current best evidence
- To improve patient care by outlining the appropriate information-gathering and decision-making processes involved in managing the diagnosis of CTS

## **TARGET POPULATION**

Adults with suspected carpal tunnel syndrome

## **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Patient history
2. Physical examination
  - Personal characteristics
  - Sensory examination
  - Manual muscle testing of the upper extremity
  - Provocative and discriminatory tests for alternative diagnoses
3. Electrodiagnostic tests

Interventions considered but not recommended for routine use include magnetic resonance imaging, computerized axial tomography, and pressure specified sensorimotor devices.

## **MAJOR OUTCOMES CONSIDERED**

Sensitivity and specificity of diagnostic tests

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

#### **Literature Searches**

In general, the Work Group did not search for or include all available evidence. Rather, the Work Group searched for and included only the best available evidence. In general, there was not a sufficient amount of Level I or II evidence available to answer any of the five key questions. The total amount of literature available on carpal tunnel syndrome and various diagnostic tests is large; however, the literature base available for individual diagnostic tests is small. A wide variety of tests are reported as well as a plethora of methods. Generally, Level III evidence and lower was found and, hence, the quality of available research studies contributed to the inherent weaknesses in the recommendations.

Search strategies were reviewed by the Work Group prior to conducting the searches. Work Group members supplemented the searches of electronic databases with articles not identified by those searches. The search strategies used are provided below.

### **Databases Searched**

The compressed timeframe for this guideline required that steps be taken to expedite work. Specifically:

1. The Work Group had to rely on published, evidence-based guidelines, published systematic reviews, and published meta-analyses before searching for clinical studies. However, at the discretion of the Work Group, we also conducted supplemental searches for some studies. These supplemental searches were restricted to searches for articles published after the end date of the searches described in the guideline/systematic review/meta-analysis.
2. The Work Group was unable to search some commonly used databases (e.g., Embase) due to time constraints. Therefore, the Work Group almost exclusively relied on PubMed/Medline for locating clinical studies.

### **Search Strategies**

The published literature was searched using the Medline electronic database to identify potentially relevant studies that shed light on the questions. A manual search was performed of the bibliographies of all publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent review articles were searched for potentially relevant citations.

The Medline search included the following search strategies, with limits of publication dates 1966 to present, English language, and humans:

Questions 1 & 2: (((("Diagnosis"[MeSH] OR "diagnosis"[Subheading] OR diagnosis[Text Word]) AND ("Carpal Tunnel Syndrome"[MeSH] OR ("carpal tunnel syndrome"[TIAB] NOT Medline[SB]) OR "carpal tunnel syndrome"[MeSH Terms] OR carpal tunnel[Text Word]))) OR "Carpal Tunnel Syndrome/diagnosis"[MeSH]) AND ("Sensitivity and Specificity"[MeSH] OR "Predictive Value of Tests"[MeSH] OR "Comparative Study"[MeSH]))

Questions 3, 4 & 5: (("Diagnosis"[MeSH] OR "diagnosis"[Subheading] OR ("diagnosis"[Subheading] OR "diagnosis"[MeSH Terms] OR diagnosis[Text Word])) AND ("Carpal Tunnel Syndrome"[MeSH] OR "Carpal Tunnel Syndrome"[All

Fields] OR "Median Neuropathy"[All Fields] OR (("carpal tunnel syndrome"[TIAB] NOT Medline[SB]) OR "carpal tunnel syndrome"[MeSH Terms] OR carpal tunnel[Text Word])) OR "Carpal Tunnel Syndrome/diagnosis"[MeSH]

Additionally, a list of potentially relevant studies was provided by the Work Group members. These citations were screened in the same manner as those identified by electronic searches.

### **Exclusion Criteria**

During Phase I screening (see Figures 1-4 in the original guideline document), all abstracts were downloaded, reviewed, and evaluated for the following exclusion criteria:

- Reviews, practice guidelines, meta-analyses (except those regarding diagnosis)
- Letters, case reports, historical articles, editorials, and commentaries
- Abstracts and unpublished study reports
- Non prospective studies
- Animal or in vitro studies
- Cadaveric studies
- Studies written in languages other than English
- Studies with <10 patients
- Studies with patients under 21 years of age
- Studies where gender is restricted
- Studies where limb temperature was not monitored during electrodiagnostic tests
- Studies where results for carpal tunnel syndrome (CTS) population cannot be separated from results from other populations
- Industrial and familial diagnoses of CTS
- Studies not pertaining to diagnosis of CTS

### **Inclusion Criteria**

Full articles were retrieved for all abstracts passing Phase I screening. The articles then underwent Phase II screening, which consisted of evaluating the articles for the following inclusion criteria:

- Studies that meet this review's reference standard (defined as signs and symptoms and nerve conduction study outcomes consistent with CTS) to confirm the diagnosis of CTS. (Questions 1 & 2)
- Studies addressing any diagnostic test to establish or support a diagnosis of CTS
- The following study designs: observational [cohort, case-control, and cross sectional (XS)], or interventional [RCTs, non-randomized controlled trials (nRCTs), XS]
- Studies that compare a minimum of two diagnostic tests (Questions 1 & 2)
- Studies where the limb temperature of the CTS patient is continuously monitored during electrodiagnostic testing according to the American Association of Electrodiagnostic Medicine Practice Parameter
- Studies where data can be abstracted for statistical analysis
- Studies reporting at least one of the following specific interventions:

- Open or Endoscopic Carpal Tunnel Release. (Question 4)
- Splinting, steroid injection or change in lifestyle. (Question 5)
- Studies reporting at least one of the following specific outcomes:
  - Post surgical improvement or resolution of CTS signs and symptoms, test results, or patient satisfaction. (Question 4)
  - Post treatment improvement or resolution of CTS signs and symptoms, test results, or patient satisfaction following splinting, steroid injection or change in lifestyle. (Question 5)

The most recent version of multiple publications was always used.

## NUMBER OF SOURCE DOCUMENTS

The initial search in PubMed yielded 424 citations for questions 1 and 2, and 1,710 citations for questions 3, 4, and 5. An additional 234 citations were identified from a manual search of reference lists and from studies provided by the Work Group members. After screening these citations, 99 studies were potentially eligible for data extraction.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

### Levels of Evidence for Primary Research Question<sup>1</sup>

	Types of Studies			
	<b>Therapeutic Studies</b> Investigating the results of treatment	<b>Prognostic Studies</b> Investigating the effects of a patient characteristic on the outcome of disease	<b>Diagnostic Studies</b> Investigating a diagnostic test	<b>Economic and Decision Analyses</b> Developing an economic or decision model
Level I	<ul style="list-style-type: none"> <li>• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>• Systematic review<sup>2</sup> of Level I randomized controlled trials (RCTs) (and study results)</li> </ul>	<ul style="list-style-type: none"> <li>• High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq 80\%</math> follow-up of enrolled patients)</li> <li>• Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>• Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>• Systematic review<sup>2</sup> of Level I studies</li> </ul>

<b>Types of Studies</b>				
	<b>Therapeutic Studies</b> Investigating the results of treatment	<b>Prognostic Studies</b> Investigating the effects of a patient characteristic on the outcome of disease	<b>Diagnostic Studies</b> Investigating a diagnostic test	<b>Economic and Decision Analyses</b> Developing an economic or decision model
	were homogenous <sup>3</sup> )			
Level II	<ul style="list-style-type: none"> <li>• Lesser quality RCT (e.g., &lt;80% follow-up, no blinding, or improper randomization)</li> <li>• Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level II studies or Level I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>• Retrospective study<sup>6</sup></li> <li>• Untreated controls from an RCT</li> <li>• Lesser quality prospective study (e.g., patients enrolled at different points in their disease or ≤80% follow-up)</li> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>• Case control study<sup>7</sup></li> <li>• Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Case control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Study of nonconsecutive patients; without consistently applied reference "gold" standard</li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses based on limited alternatives and costs; and poor estimates</li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	<ul style="list-style-type: none"> <li>• Case series<sup>8</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Case series</li> </ul>	<ul style="list-style-type: none"> <li>• Case-control study</li> <li>• Poor reference standard</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses with no sensitivity analyses</li> </ul>
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

<sup>1</sup> A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>2</sup> A combination of results from two or more prior studies.

<sup>3</sup> Studies provided consistent results.

<sup>4</sup> Study was started before the first patient enrolled.

<sup>5</sup> Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated

in another way (e.g., uncemented hip arthroplasty) at the same institution.

<sup>6</sup> The study was started after the first patient enrolled.

<sup>7</sup> Patients identified for the study based on their outcome, called "cases"; e.g., failed total hip arthroplasty, are compared to those who did not have outcome, called "controls"; e.g., successful total hip arthroplasty.

<sup>8</sup> Patients treated one way with no comparison group of patients treated in another way.

## **METHODS USED TO ANALYZE THE EVIDENCE**

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

### **Data Extraction**

Four reviewers completed data extraction independently for all studies, except for studies where data were extracted by one reviewer and checked by another. Any disagreements were resolved by consensus. Evidence tables were constructed to summarize the best evidence pertaining to each key question.

The following data categories were extracted into electronic forms in Microsoft® Access or Excel (see Appendix C in the original guideline document).

- Study characteristics (authors, publication year, study design, study duration, follow up period, total number of patients enrolled or hands tested, diagnostic test or treatment intervention, level of evidence)
- Patient characteristics (age—mean, median, and range, gender distribution, criteria for diagnosing carpal tunnel syndrome [CTS], duration of symptoms—mean and range, patient exclusion criteria, severity of CTS—mild, moderate, or severe)
- Diagnostic tests (2 X 2 tables—number of true positives, true negatives, false positives, and false negatives, sensitivity, specificity, negative and positive likelihood ratios, negative and positive predictive value, percent of patients with positive test results, pre- and post treatment test results—mean and standard deviation)
- Treatment outcomes (type of outcomes, change in outcomes—mean and standard deviation, percent of patients with positive treatment outcomes)

### **Analysis**

The purpose of the statistical analysis was to assess the diagnostic accuracy of various tests commonly used to diagnose carpal tunnel syndrome. Measures of diagnostic accuracy are based on the comparison of a test with a reference standard that determines the presence or absence of CTS. For this analysis, signs and symptoms of CTS and electrodiagnostic test (Questions 1 & 2); symptoms of CTS (Question 3); surgical outcomes from open or endoscopic carpal tunnel release (Question 4); and disease status (Question 5) were used as the "gold" standards.

In order to be considered for the analysis, studies had to report outcomes in terms of the sensitivity and specificity or had sufficient information on the performance of the test regarding the true positive and true negative outcomes (or likelihood ratios) in order to calculate sensitivity and specificity. Studies also had to have tests, outcome measures or durations of follow up in common to perform meta-analysis. Given the paucity and heterogeneity of the data for specific questions, the guideline developers did not perform meta-analytic techniques in all circumstances. When possible, effect sizes were pooled across different studies, and heterogeneity was assessed with I-squared statistic.

The guideline developers attempted to meta-analytically construct receiver operating characteristic (ROC) curves for each diagnostic group or individual tests where sufficient data were available. These curves described how the test's performance in those with CTS (sensitivity or true positive rate) varies with its performance in those without CTS (false positive rate or 1 - specificity). The area under the curve (AUC) provides a measure of the overall accuracy of a test. All ROC curves were calculated using Meta-DiSc version 1.4 and Comprehensive Meta Analysis version 2. Due to unexplained heterogeneity, the guideline developers did not complete these meta-analyses.

Meta-analyses were also performed to pool the clinical outcomes of patients treated surgically with carpal tunnel release and to compare different individual and groups of diagnostic tests. Based on available data, meta-analyses were conducted for the diagnosis and surgery studies to determine whether clinical, electrodiagnostic, or clinical plus electrodiagnostic test results were associated with surgical outcomes. A meta-analysis of carpal tunnel surgery data examined pre-post surgery standardized mean differences in electrodiagnostic test results. Meta-regressions that consider diagnostic tests as predictors of surgical outcomes were examined as well. These meta-regressions employed the permutation method of Higgins & Thompson 2004. Several subgroup analyses were performed to identify factors that may be related to diagnostic variations. All meta-analyses and meta-regressions were performed using Stata 9.2 (StataCorp LP, College Station, Texas).

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus (Nominal Group Technique)

### **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

The 8 member Work Group of experts in orthopaedic surgery, plastic surgery, physical medicine and rehabilitation, and electrodiagnostic medicine proposed recommendations for the diagnosis of carpal tunnel syndrome. American Academy of Orthopaedic Surgeons (AAOS) staff provided identification and critical appraisal of key studies, and ratings of the quality of the evidence that correspond to each recommendation. The resulting summary of proposed conclusions and recommendations for consideration was presented and deliberated upon by members of the Work Group in a meeting on February 24, 2007.

Voting on guideline recommendations and performance measures was conducted using a modification of the nominal group technique, a method previously used in



guideline development. In this modification each Work Group member ranked a recommendation or performance measure on a scale ranging from 1 ("extremely appropriate") to 9 ("extremely inappropriate"). One Work Group member could not participate in the face-to-face meeting, hence the American Academy of Orthopaedic Surgeons Guideline Oversight Committee Chairperson, William C. Watters III MD, substituted as an alternate member via teleconference for voting purposes. For the purposes of this guideline, consensus was obtained when/if six (6) of seven (7) Work Group members ranked the recommendation or measure as a 7, 8, or 9. When two (2) or more Work Group members did not rank a measure in this range, three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted. The final recommendations were refined via a teleconference call on March 17, 2007 with all members of the Work Group present.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Recommendation Grades**

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention

B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention

C: Poor-quality evidence (Level IV or V) for or against recommending intervention

I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Grading Recommendations Specific to the carpal tunnel syndrome (CTS)  
Guideline: When studies employ readers who were not blinded to each other and/or to the symptoms of the patient, we downgraded the quality of a study by one level of evidence (i.e., unblinded studies introduce the possibility of bias).

### **Relevant Issues:**

The Committee recognized the following language in constructing the recommendations: Strong Recommendation (Must), Recommendation (Should), Option (May), or no recommendation. These definitions help clarify the intent of the Work Group by reflecting the assessment of the importance of adherence to the recommendation based on the grade level of the recommendation.

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

March 24, 2007: Approved by the American Academy of Orthopaedic Surgeons (AAOS) Guideline Oversight Committee

March 24, 2007: Approved by the AAOS Evidence Based Practice Committee

May 7, 2007: Approved by the AAOS Council on Research, Quality Assessment and Technology

May 18, 2007: Approved by the AAOS Board of Directors

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I-V) and grades of recommendation (A-C, I) and are provided at the end of the "Major Recommendations" field.

#### Recommendation 1.1

The physician should obtain an accurate patient history (**Level V, Grade C**).

#### Recommendation 2.1

The physician should perform a physical examination of the patient that may include:

- Personal characteristics (**Level V, Grade C**)
- Performing a sensory examination (**Level V, Grade C**)
- Performing manual muscle testing of the upper extremity (**Level V, Grade C**)
- Performing provocative tests (**Level V, Grade C**), and/or
- Performing discriminatory tests for alternative diagnoses (**Level V, Grade C**)

#### Recommendation 3.1a

The physician may obtain electrodiagnostic tests to differentiate among diagnoses. (**Level V, Grade C**)

#### Recommendation 3.1b

The physician may obtain electrodiagnostic tests in the presence of thenar atrophy and/or persistent numbness (**Level V, Grade C**).

#### Recommendation 3.1c

The physician should obtain electrodiagnostic tests if clinical and/or provocative tests are positive and surgical management is being considered (**Level II and III, Grade B**)

### Recommendation 3.2

If the physician orders electrodiagnostic tests, the testing protocol should follow the American Academy of Neurology/American Association of Neuromuscular and Electrodiagnostic Medicine/American Academy of Physical Medicine and Rehabilitation (AAN/AANEM/AAPMR) guidelines for diagnosis of carpal tunnel syndrome (CTS) (**Level IV and V, Grade C**).

### Recommendation 3.3

The physician should not routinely evaluate patients suspected of having carpal tunnel syndrome with new technology, such as magnetic resonance imaging (MRI), computerized axial tomography (CAT), and pressure specified sensorimotor devices (PSSD) in the wrist and hand. (**Level V, Grade C**).

Please note that Recommendation 3.3 is not based on a systematic literature review. An additional abbreviated review was completed following the face to face meeting of the Work Group on February 24, 2007.

### Definitions:

### Levels of Evidence for Primary Research Question<sup>1</sup>

Types of Studies				
	<b>Therapeutic Studies</b> Investigating the results of treatment	<b>Prognostic Studies</b> Investigating the effects of a patient characteristic on the outcome of disease	<b>Diagnostic Studies</b> Investigating a diagnostic test	<b>Economic and Decision Analyses</b> Developing an economic or decision model
Level I	<ul style="list-style-type: none"><li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li><li>Systematic review<sup>2</sup> of Level I randomized controlled trials (RCTs) (and study results were homogenous<sup>3</sup>)</li></ul>	<ul style="list-style-type: none"><li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq 80\%</math> follow-up of enrolled patients)</li><li>Systematic review<sup>2</sup> of Level I studies</li></ul>	<ul style="list-style-type: none"><li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li><li>Systematic review<sup>2</sup> of Level I studies</li></ul>	<ul style="list-style-type: none"><li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li><li>Systematic review<sup>2</sup> of Level I studies</li></ul>
Level II	<ul style="list-style-type: none"><li>Lesser quality RCT (e.g., <math>&lt;80\%</math>)</li></ul>	<ul style="list-style-type: none"><li>Retrospective study<sup>6</sup></li></ul>	<ul style="list-style-type: none"><li>Development of diagnostic</li></ul>	<ul style="list-style-type: none"><li>Sensible costs and</li></ul>

Types of Studies				
	<b>Therapeutic Studies</b> Investigating the results of treatment	<b>Prognostic Studies</b> Investigating the effects of a patient characteristic on the outcome of disease	<b>Diagnostic Studies</b> Investigating a diagnostic test	<b>Economic and Decision Analyses</b> Developing an economic or decision model
	follow-up, no blinding, or improper randomization) <ul style="list-style-type: none"> <li>• Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level II studies or Level I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>• Untreated controls from an RCT</li> <li>• Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <math>\leq 80\%</math> follow-up)</li> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>	criteria on consecutive patients (with universally applied reference "gold" standard) <ul style="list-style-type: none"> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>	alternatives; values obtained from limited studies; with multiway sensitivity analyses <ul style="list-style-type: none"> <li>• Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>• Case control study<sup>7</sup></li> <li>• Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Case control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Study of nonconsecutive patients; without consistently applied reference "gold" standard</li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses based on limited alternatives and costs; and poor estimates</li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	<ul style="list-style-type: none"> <li>• Case series<sup>8</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Case series</li> </ul>	<ul style="list-style-type: none"> <li>• Case-control study</li> <li>• Poor reference standard</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses with no sensitivity analyses</li> </ul>
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

<sup>1</sup> A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>2</sup> A combination of results from two or more prior studies.

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<sup>6</sup> The study was started after the first patient enrolled.

<sup>7</sup> Patients identified for the study based on their outcome, called "cases"; e.g., failed total hip arthroplasty, are compared to those who did not have outcome, called "controls"; e.g., successful total hip arthroplasty.

<sup>8</sup> Patients treated one way with no comparison group of patients treated in another way.

## Recommendation Grades

**A:** Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

**B:** Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

**C:** Poor-quality evidence (Level IV or V) for or against recommending intervention.

**I:** There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Grading Recommendations Specific to the CTS Guideline: When studies employ readers who were not blinded to each other and/or to the symptoms of the patient, we downgraded the quality of a study by one level of evidence (i.e., unblinded studies introduce the possibility of bias).

## Relevant Issues:

The Committee recognized the following language in constructing the recommendations: Strong Recommendation (Must), Recommendation (Should), Option (May), or no recommendation. These definitions help clarify the intent of the Work Group by reflecting the assessment of the importance of adherence to the recommendation based on the grade level of the recommendation.

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Accurate diagnosis of carpal tunnel syndrome

### POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- This clinical guideline was developed by an American Academy of Orthopaedic Surgeons physician volunteer Work Group and is provided as an educational tool based on an assessment of the current scientific and clinical information and accepted approaches to treatment. It is not intended to be a fixed protocol as some patients may require more or less treatment. Patient care and treatment should always be based on a clinician's independent medical judgment given the individual clinical circumstances.
- This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

### Limitations of the Evidence Base

- The major limitations of this systematic review are related to weaknesses inherent in the available published literature on the diagnosis of carpal tunnel syndrome (CTS). For each key question the highest level of evidence (randomized controlled trials [RCTs] and systematic reviews of RCTs) was initially sought. Due to the paucity of such studies, non-randomized comparative trials (e.g., cross-sectional, case-control, cohort studies) were also considered for all questions.
- Frequently, these studies were subject to spectrum bias and there was no blinded assessment of test results. In several studies there was no statistical analysis and the follow-up periods differed between the groups. Methodological rigor of the included studies, therefore, was low to medium.
- Many studies were excluded from this review due to insufficient data or unreported limb temperature during electrodiagnostic testing (see Appendix D in the original guideline document). While strict application of inclusion and exclusion criteria caused some pertinent and potentially useful studies to be excluded, this review sought to apply uniform criteria that were established a priori. Even with these restrictions, a sufficient number of studies met inclusion criteria to address most of the key questions.
- Another limitation of this review is that it was limited to published studies only. As studies with unfavorable results are often not published, the accuracy of a reference standard, such as positive surgical outcome, may appear falsely elevated. Test of publication bias conducted among a few studies of electrodiagnostic testing, however, did not find the presence of publication bias.
- Case-mix (selection or spectrum) bias occurs when cases are selected that inaccurately reflect the range of cases that occur in the general population. This was particularly true for case-control studies in which case selection generally favored selecting patients with the most advanced disease and the healthiest controls. A study using these easier cases to diagnose is more likely to show a favorable result than when the diagnostic test is used in general practice.
- While most studies reported diagnostic results, these results were reported in a wide variety of formats. The variable quality and diversity of tests interfered

with the ability to statistically amass a coherent body of evidence. Treatment outcomes, such as functional and surgical status, were described with such wide variation that the results from different studies could not be readily combined in a meaningful way to determine if they correlated with the diagnostic test of interest.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Orthopaedic Surgeons clinical guideline on diagnosis of carpal tunnel syndrome. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2007. 72 p. [381 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

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### GUIDELINE DEVELOPER(S)

American Academy of Orthopaedic Surgeons - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

American Academy of Orthopaedic Surgeons

## **GUIDELINE COMMITTEE**

American Academy of Orthopaedic Surgeons (AAOS) Carpal Tunnel Syndrome (CTS) Diagnosis Guideline Work Group

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

All panel members gave full disclosure of conflicts of interest prior to voting on the recommendations contained within these guidelines. No member on the Carpal Tunnel Syndrome Diagnosis Guideline Work Group disclosed a conflict of interest.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Academy of Orthopaedic Surgeons Web site](http://www.aaos.org).

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: [www.aaos.org](http://www.aaos.org).

## **AVAILABILITY OF COMPANION DOCUMENTS**



The following is available:

- Diagnosis of carpal tunnel syndrome. Evidence report. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2007. Various p.

Electronic copies: Available in Portable Document Format (PDF) from the [American Academy of Orthopaedic Surgeons Web site](#).

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: [www.aaos.org](http://www.aaos.org).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on July 10, 2007. The information was verified by the guideline developer on July 26, 2007.

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